

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
18 December 2003 (18.12.2003)

PCT

(10) International Publication Number
WO 2003/103706 A3

(51) International Patent Classification⁷: **A61K 39/39**,
38/17, A61P 35/00, C07K 14/47, 14/705, C12N 15/63,
15/12, 5/10

(74) Agent: DALTON, Marcus, Jonathan, Wt; Glaxo-
SmithKline, CN925.1, 980 Great West Road, Brentford,
Middlesex TW8 9GS (GB).

(21) International Application Number:
PCT/EP2003/006095

(22) International Filing Date: 6 June 2003 (06.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0213364.3 11 June 2002 (11.06.2002) GB
0221689.3 18 September 2002 (18.09.2002) GB

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD,
SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US,
UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicants (*for all designated States except US*): GLAXO-
SMITHKLINE BIOLOGICALS S.A. [BE/BE]; Rue de
l'Institut 89, B-1330 Rixensart Brussels (BE). GLAXO
GROUP LIMITED [GB/GB]; Glaxo Wellcome House,
Berkeley Avenue, Greenford, Middlesex UB6 ONN (GB).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): CASSART,
Jean-Pol [BE/BE]; GlaxoSmithKline Biologicals s.a.,
Rue de l'Institut 89, B-1330 Rixensart Brussels (BE).
GERARD, Catherine, Marie, Ghislaine [BE/BE]; Glaxo-
SmithKline Biologicals s.a., Rue de l'Institut 89, B-1330
Rixensart Brussels (BE). HAMBLIN, Paul, A [GB/GB];
GlaxoSmithKline, Gunnels Wood Road, Stevenage,
Hertfordshire SG1 2NY (GB). PALMANTIER, Remi,
M [FR/BE]; GlaxoSmithKline Biologicals s.a., Rue de
l'Institut 89, B-1330 Rixensart Brussels (BE).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
19 February 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMMUNOGENIC COMPOSITIONS COMPRISING A XENOGENIC PROSTATE PROTEIN P501S

(57) Abstract: The present invention relates to pharmaceutical/immunogenic compositions and methods for inducing an immune response against tumour-related antigens. More specifically, the invention relates to non-human prostate-specific antigens, more precisely to the non-human prostate-specific P501S, which can be used as xenogeneic antigen in prostate cancer vaccine therapy and as diagnostic agents for prostate tumours in humans, to immunogenic compositions containing them, to methods of manufacture of such compositions and to their use in medicine. Methods for formulating vaccines for immunotherapeutically treating P501S-expressing prostate tumors, prostatic hyperplasia, and prostate intraepithelial neoplasia (PIN) are also provided.

WO 2003/103706 A3

INTERNATIONAL SEARCH REPORT

Inter Application No
PCT/03/06095

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/39 A61K38/17 A61P35/00 C07K14/47 C07K14/705
C12N15/63 C12N15/12 C12N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBL, SEQUENCE SEARCH, WPI Data, EMBASE, MEDLINE, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00 04149 A (CORIXA CORP) 27 January 2000 (2000-01-27)	1-27
X	page 63; examples 1,8	1
Y	WO 98 46769 A (SHAPERO MICHAEL H ;DENDREON CORP (US); LAUS REINER (US); RUEGG CUR) 22 October 1998 (1998-10-22) page 2	1-27
Y	WO 01 81577 A (SCHERING AG ;SCHNEIDER DOUGLAS W (US); STEINBRECHER RENATE (US); L) 1 November 2001 (2001-11-01) page 34, paragraph 2	1-27
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

21 November 2003

Date of mailing of the international search report

09/12/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Wagner, R

INTERNATIONAL SEARCH REPORT

 Intern Application No
 PCT/03/06095

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>XU JIANGCHUN ET AL: "Identification and characterization of prostein, a novel prostate-specific protein" CANCER RESEARCH, vol. 61, no. 4, 15 February 2001 (2001-02-15), pages 1563-1568, XP002262454 ISSN: 0008-5472 figure 1</p>	1-27
Y	<p>FONG L ET AL: "INDUCTION OF TISSUE-SPECIFIC AUTOIMMUNE PROSTATITIS WITH PROSTATIC ACID PHOSPHATASE IMMUNIZATION" JOURNAL OF IMMUNOLOGY, THE WILLIAMS AND WILKINS CO. BALTIMORE, US, vol. 159, no. 7, 1 October 1997 (1997-10-01), pages 3113-3117, XP002068783 ISSN: 0022-1767 page 3117</p>	1-27
Y	<p>HODGE J W ET AL: "A RECOMBINANT VACCINIA VIRUS EXPRESSING HUMAN PROSTATE-SPECIFIC ANTIGEN (PSA): SAFETY AND IMMUNOGENICITY IN A NON-HUMAN PRIMATE" INTERNATIONAL JOURNAL OF CANCER, NEW YORK, NY, US, vol. 63, no. 2, 9 October 1995 (1995-10-09), pages 231-237, XP000604553 ISSN: 0020-7136 abstract</p>	1-27
P,X	<p>DATABASE EBI 'Online! EMBL; 1 October 2002 (2002-10-01) FANTOM CONSORTIUM: "hypothetical protein - (Prostein homolog)" retrieved from HTTP://WWW.EBI.AC.UK Database accession no. Q8K0H7 XP002262455 abstract & OKAZAKI ET AL: "Analysis of the mouse transcriptome based on functional annotation of 60,770 full-length cDNAs" NATURE , vol. 420, no. 6915, 5 December 2002 (2002-12-05), pages 563-573, XP002252038 page 8</p>	9-13

-/--

INTERNATIONAL SEARCH REPORT

Inter Application No
PCT/ 93/06095

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>NAFTZGER C ET AL: "Immune response to a differentiation antigen induced by altered antigen: A study of tumor rejection and autoimmunity"</p> <p>PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, vol. 93, no. 25, 1996, pages 14809-14814, XP002188976</p> <p>ISSN: 0027-8424</p> <p>the whole document</p> <p>----</p>	1-27
A	<p>WO 01 25273 A (CORIXA CORP ; REED STEVEN G (US); XU JIANGCHUN (US); CHEEVER MARTIN)</p> <p>12 April 2001 (2001-04-12)</p> <p>the whole document</p> <p>----</p>	1-27
A	<p>WO 99 46992 A (GREGORY RICHARD J ; GENZYME CORP (US); KAPLAN JOHANNE (US))</p> <p>23 September 1999 (1999-09-23)</p> <p>the whole document</p> <p>-----</p>	5

INTERNATIONAL SEARCH REPORT

Ir

Application No.
PCT/EP 03/06095**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 23-27 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern Application No

PCT/3/06095

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0004149	A	27-01-2000	US 2002090372 A1	11-07-2002
			US 6613872 B1	02-09-2003
			US 2002182596 A1	05-12-2002
			US 6465611 B1	15-10-2002
			AU 762812 B2	03-07-2003
			AU 5314899 A	07-02-2000
			BR 9912007 A	29-01-2002
			CA 2334038 A1	27-01-2000
			CN 1315998 T	03-10-2001
			CZ 20010149 A3	13-02-2002
			EP 1097208 A2	09-05-2001
			HU 0203035 A2	28-12-2002
			JP 2002520054 T	09-07-2002
			NO 20010196 A	12-03-2001
			PL 346359 A1	11-02-2002
			US 2003088062 A1	08-05-2003
			WO 0004149 A2	27-01-2000
			US 2003157089 A1	21-08-2003
			US 2003185830 A1	02-10-2003
			US 6395278 B1	28-05-2002
			US 6329505 B1	11-12-2001
			US 6620922 B1	16-09-2003
			US 2002022248 A1	21-02-2002
			US 2002051977 A1	02-05-2002
			US 2002193296 A1	19-12-2002
WO 9846769	A	22-10-1998	AU 6897998 A	11-11-1998
			EP 0973916 A1	26-01-2000
			JP 2001516226 T	25-09-2001
			WO 9846769 A1	22-10-1998
WO 0181577	A	01-11-2001	US 2002009455 A1	24-01-2002
			AU 5725201 A	07-11-2001
			EP 1278842 A2	29-01-2003
			NO 20025168 A	23-12-2002
			WO 0181577 A2	01-11-2001
WO 0125273	A	12-04-2001	AU 7859900 A	10-05-2001
			WO 0125273 A2	12-04-2001
WO 9946992	A	23-09-1999	AU 758265 B2	20-03-2003
			AU 3102999 A	11-10-1999
			CA 2322624 A1	23-09-1999
			EP 1071333 A1	31-01-2001
			JP 2002506618 T	05-03-2002
			WO 9946992 A1	23-09-1999